JUL 1 9 2000

K001936

510(k) Summary of Safety and Effectiveness
ArthroCare Corporation
ENTec® Surgery System , ArthroCare® Orthopedic Surgery System, and ArthroCare® Electrosurgery System (Electrosurgery Systems)

General Information

Manufacturer:

ArthroCare, Corporation
595 North Pastoria Avenue
Sunnyvale, CA 94086-2916

Establishment Registration Number: 2951580

Contact Person:

Betty M. Johnson
Manager, Regulatory Affairs

Date Prepared: June 22, 2000

Device Description

Classification Name:

Electrosurgical Cutting and Coagulation Device and Accessories (21 CFR 878.4400)

Trade Name:

ENTec® Surgery System
ArthroCare® Orthopedic Electrosurgery System
ArthroCare® Electrosurgery System

Generic/Common Name: Electrosurgical Device and Accessories

Predicate Devices

- ENTec Surgery System — K973478
- ArthroCare Orthopedic Electrosurgery System — K992581
- ArthroCare Electrosurgery System — K001302

Intended Uses

- The ENTec Surgery System is intended for ablation and coagulation of soft tissue in otorhinolaryngology (ENT) surgery including head, neck, oral, and sinus surgery.

- The ArthroCare Orthopedic Electrosurgery System is indicated for resection, ablation, and coagulation of soft tissues and hemostasis of blood vessels in orthopedic, arthroscopic, and spinal procedures.

- The ArthroCare Electrosurgery System is indicated for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in general, plastic, and reconstructive surgery. It is intended to be used in procedures using conductive solutions, such as normal saline.

Product Description

The ArthroCare Electrosurgery Systems are bipolar, high frequency electrosurgical Systems consisting of three components: an electrosurgical generator called the Controller, the disposable Wand, and the reusable Cable.

Substantial Equivalence

This Special 510(k) proposes modifications in materials, performance, dimensional specifications, and packaging parameters to the Wand component of the Electrosurgery Systems, which were previously cleared in K973478 on January 9, 1998, K992581 on December 9, 1999, and K001302 on May 30, 2000. The proposed modifications are applicable to the Wand component of the Electrosurgery Systems, as well as to the packaging materials. The technology, principle of operation and the intended uses of the Electrosurgery Systems remain the same as in the predicate cleared 510(k)s.

Summary of Safety and Effectiveness

The modified Wand component of the Electrosurgery Systems, as described in this submission, is substantially equivalent to the predicate Wands. The proposed modifications in materials, performance specifications, and dimensional specifications are not substantial changes or modifications, and do not significantly affect the safety or efficacy of the devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 9 2000

Ms. Betty M. Johnson
Manager, Regulatory Affairs
ArthroCare Corporation
595 North Pastoria Avenue
Sunnyvale, California 94086-2916

Re: K001936
Trade Name: ENTec® Surgery System
ArthroCare® Orthopedic Electrosurgery System
ArthroCare® Electrosurgery System
Regulatory Class: II
Product Code: GEI
Dated: June 22, 2000
Received: June 26, 2000

Dear Ms. Johnson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications Statement

Device Names: ENTec® Surgery System
ArthroCare® Orthopedic Electrosurgery System
ArthroCare® Electrosurgery System

510(k) Number: K 001936

Indications for use:

- The ENTec Surgery System is intended for ablation and coagulation of soft tissue in otorhinolaryngology (ENT) surgery including head, neck, oral, and sinus surgery.
- The ArthroCare Orthopedic Electrosurgery System is indicated for resection, ablation, and coagulation of soft tissues and hemostasis of blood vessels in orthopedic, arthroscopic, and spinal procedures.
- The ArthroCare Electrosurgery System is indicated for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in general, plastic, and reconstructive surgery. It is intended to be used in procedures using conductive solutions, such as normal saline.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001936

Prescription Use (Per 21 CFR 801.109)	X	OR	Over-the-Counter Use	